

# SPL Process Meeting

## Meeting Minutes

### December 4, 2013

Chair of today's meeting: Mary Beth Wilucz

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

\*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

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## **New Discussion Topics:**

1. Question regarding Company experience regarding the following (Kathleen Linn)

Per The Guidance for Industry – Self-Identification of Generic Drug Facilities, Sites, and Organizations states the following:

**FDA will assign only one FEI number to separate buildings if they are in close proximity and if the activities conducted in each building are closely related to the same business enterprise, are under the supervision of the same local management,<sup>5</sup> and are capable of being inspected by FDA during a single inspection.**

We have a facility that has both a terminal sterilization and aseptic sterilization building. The team is asking if these two buildings that appear on the same campus can be assigned different FEI numbers.

Does anyone have any experience with the above request?

- Most companies have one FEI and one DUNS number for a campus.
- Reason for the company wanting to do this: If there is a quality issue with one facility that would prevent import, then material being shipped in from the other facility would not be affected.

- GSK: Within the last year, multiple labs within the same campus/building have been assigned separate FEI numbers. Each also has its own DUNS number. These have each been submitted and appear on the DECRS site.
- Other considerations:
  - o This has implications for manufacturing establishments – multiple FEIs would each be assessed establishment fees
  - o If you assign multiple FEIs for buildings in this campus, are you maintain consistency across multiple establishments within your DER
  - o How do you handle a single building that does multiple operations within the building
  - o Two different FEIs might trigger more inspections – since multiple FEI numbers are involved.

2. Is there a way to file so that the FDA knows not to disclose proprietary information on Daily Med? (Samantha Hanagan)

## HOLDOVER TO THE NEXT MEETING

3. Establishment registrations (Ken Stevenson)

### Scenario

Client A is a domestic PLD having its own label and labeler code. Client B is a foreign manufacturer with a domestic facility to which drug products are shipped. The foreign facility belonging to Client B is an FDA registered drug establishment but the registration is for the single foreign establishment. The domestic facility belonging to Client B is not an FDA registered facility. Client A is coordinating the manufacture of an OTC product that Client B will manufacture at its foreign facility. The product will then be shipped from Client B's foreign facility, to Client B's domestic facility. Although Client A is a PLD, this particular product belongs to Client B and will be delivered turnkey to Client A. At that point Client A will simply distribute the finished OTC. My only role in the process is assistance with SPL and Establishment Registration.

My questions are these:

1. What establishment registrations/business operations are necessary for this product to reach final distribution without issue or delay?
  - Does Client A need to register its facility? As they are currently only a PLD and have no establishment registration will they need to submit establishment registration for this scenario? Since Client A's only roles in this scenario are to coordinate the process and final distribution should they register there establishment and if so what business operations should be included?
  - How should Client B register its domestic facility for this OTC Product? What business operations? Assuming that the domestic facility already has a DUNS.
  - Will Client B need to add any additional business operations to their current FDA establishment registration for their foreign facility?
2. What submissions will be needed in order to correctly list this product so as to reach the final distributor without issue or delay?

- By Client A?
    - o Any additional comments or information?
  - By Client B?
    - o What information will be presented in the Data Elements section of the listing submission(s) and how will it be arranged?
    - o If the product is manufactured at Client B's foreign facility, shipped without being labeled and then labels are applied at Client B's domestic facility; how does this affect the establishment registrations, drug listings and the information therein?
3. Any additional comments or information?

## HOLDOVER TO THE NEXT MEETING

### Reminders/FYI:

#### **US agent DUNS – from 14Nov13**

Effective immediately, a validation procedure will be implemented to ensure that the DUNS Number associated with a US agent identified in an incoming establishment registration SPL document is linked to an address in the US.

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#### **ESG Help Desk email change:**

**Beginning Monday, December 2, 2013 the FDA Electronic Submissions Gateway (ESG) Help Desk email address will change to [ESGHelpDesk@fda.hhs.gov](mailto:ESGHelpDesk@fda.hhs.gov).**

Until 12/2/13, please continue to email the FDA ESG Help Desk at [esgreg@gnsi.com](mailto:esgreg@gnsi.com). After 12/2/13 all responses from the ESG Help Desk will come from [ESGHelpDesk@fda.hhs.gov](mailto:ESGHelpDesk@fda.hhs.gov). Please make sure that you can accept emails from [ESGHelpDesk@fda.hhs.gov](mailto:ESGHelpDesk@fda.hhs.gov).

Reminder to all SPL creators and maintainers: The ESG e-mail address is for questions specific to the ESG Gateway. The support group for the ESG is not tasked with supporting SPL questions, or DRLS questions, or NDC directory questions. The SPL and eDRLS email addresses have not changed.

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#### **New validation procedure:**

The following validation procedure for content of labeling/product data element SPL documents with information for designated medical gas products that have NDAs will be implemented **tomorrow, Thursday, December 5, 2013**:

4.2.1.9 If the document type is Human Prescription Drug Label (34391-3) or Prescription Animal Drug Label (50578-4) and the active ingredient is in the designated medical gas validation list, then there is at least one other content of labeling section besides those with the codes 48780-1 and 51945-4.

Here is the hyperlink to the draft of the regulatory Guidance for Industry Certification Process for Designated Medical

Gases: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM332136.pdf>.

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## Holdovers from the last meeting:

1. **D&B data issues** – Dale lanetti (Merck) is part of a pilot program and had a number of issues. Dale sent whole file to D&B to get their help in resolving their issues.
  - D&B - compared all data from all sites – so that they could determine the differences.
  - Talked through all the issues. D&B is investigating several of their issues. They are going to talk to FDA to determine if there is some flexibility in terms of allowing differences.
  - Merck will not change addresses or names, but will make minor changes in addresses if the address is still consistent. Merck also needs several new DUNS numbers because the addresses didn't match up.

\*\*\*Hold to next meeting

2. Dale lanetti: I was wondering if anyone in the group has had the opportunity to request a new FEI number for a site, and exactly what the process is. I have heard different stories and would like to know if anyone has actually done it since SPL has been in use.

\*\*\*Hold to next meeting

Charisse Kasser was involved with writing the new guidance. The FEI number will not go away, at least in the near future. At any event, the FEI will be used internally at FDA in their computer systems. Many FDA ORA systems use the FEI numbers, so the FEI number will stay.

3. **Ruth Kirkner: Download xml from DailyMed.** Has anyone had problems with text being cut off from the downloaded version of SPL – eg long black box warning. All text exists on Daily Med, but the downloaded version is wrong.

- a. It sounds like the stylesheet is not handling the text properly
- b. Suggest contacting DailyMed to alert them of the problem.
- c. Ruth will let us know outcome

## **Announcements:**

### **ESG Issue**

- ESG REG has confirmed that there is now a known issue with ESG WebTrader's Acknowledgements.
- There is a problem where user Acknowledgements are not displayed in the MySubmissions Screen, but sent to the Other Documents Folder in some but not all cases.
- ESG REG are aware of the problem and are working to fix it. In the meantime, please keep this in mind when sending submissions via the FDA WebTrader to check your Other Documents Folder for the Acknowledgements.

### **SPL/DailyMed Jamboree Workshop**

NLM is sponsoring a public meeting, "SPL/DailyMed Jamboree Workshop, on October 28, 8:30 to 3:30 – Using DailyMed Drug Product Label Data". Representatives from the brand name, generic name and OTC drug industries will speak, as well as the FDA, the NLM and possibly other government agencies.

- Terry Brunone, Marcia Howard, Virginia Hogan (generics) and others will be presenting.
- Note: I tried to register last week and the online spots were full. I was put on a wait list. There were still spots available to attend in person, as of last week.
- Marcia Howard would like to know of any unique ways they are using information from Daily Med.

**DIA Labeling Conference** -- focusing on a number of global labeling topics: how to write device labeling, patient labeling, new EU Pharmacovigilance influence on labeling, Health Canada, PMDA, etc. Steve Bass will be sending more information on this.

Timing: April 8-10, 2014

Where: Washington area